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Method and Device for Producing and Filling Containers

The invention relates to a method for producing and filling containers, a method in which at least one tube made of a softened plastic material is extruded into an open mold, the tube is heat sealed at its projecting end when the mold is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element so as to form a fill hole, and the mold, along with the tube comprising the open fill hole, is moved into a filling position in which the container is filled and then sealed after being configured in the mold by generating a pressure gradient that acts upon the tube and expands the same, whereby the fill hole of the tube is covered by a sterile barrier at least from the time said fill hole is formed to the time the respective container is filled in a sterile space. The invention also relates to a device for application of such method.

A production method and production device have been disclosed in the relevant state of the art under the trade name bottelpack®. The production method permits cost-effective

automated molding (blowing and vacuum molding), filling, and sealing of containers. If the containers in question are to be filled with high-sensitivity products such as pharmaceuticals for which international standards for aseptic packaging are to be met, the mold, when moved to the filling position, is closed in an area called the sterile filling space in which sterile air is blown over the uncovered fill opening of containers and provides effective protection from penetration by germs. Movable head jaws of the mold are closed until after completion of the filling process in order to effect the desired sealing of the end of the container by a combined vacuum and welding process. Such sterile filling areas and their devices for sterile filling of containers are of the state of the art and are disclosed, for example, by DE 196 48 087 A1 or US 6,098,686.

While the fill opening is effectively protected by the sterile filling space in the filling position, the fill opening when open is not fully protected during movement of the mold from the extrusion position, in which the tube which has been formed is separated below the extruder nozzle and the fill opening is formed, until the filling position has been reached, even if the process is conducted in a clean space. In other words, the tube having the fill opening forms an open receptacle on the upper side during movement of the mold into the filling position. In order to increase the certainty of sterility, a process and a device have already been proposed in DE 100 63 282 A1 as generic state of the art, ones which take care to make certain that the fill opening of the tube is covered by a sterile barrier during movement of the mold into the filling position. The known sterile barrier is in the form of a heatable plate which may be moved together with the element separating the tube. The plate is heated to a germ-killing temperature, preferably one above 120°C. In the process the sterile barrier is in such a position and provided with such dimensions that it is situated, when the separating element is in the operating position, above the path of movement leading to the filling position of the mold and covering the fill opening, until it has reached the sterile filling space.

Not only does this known solution prevent the danger of falling of alien bodies into the uncovered fill opening after separation of the tube before the mold has reached the sterile filling

space but the sterile barrier also prevents access of germs to the fill opening during this part of the process, so that the desired freedom from germs has been achieved to a very great extent.

On the basis of this proximate state of the art the object of the invention is to optimize the known solution even further as regards improvement in freedom from germs in the area of the fill opening of a container, in order to provide the possibility of introducing high-sensitivity products for the medical/pharmaceutical area of application into the containers. The object as thus formulated is attained by a method having the characteristics specified in claim 1 in its entirety and by a device having the characteristics specified in claim 9.

In that, in the matter of the method and associated device claimed for the invention in the characterizing portion of claim 1 and in claim 9, by means of the sterile barrier at least one sterile medium is moved by means of a medium conveying device in the direction of the fill opening of the tube, immediately after separation of the tube by means of the separating element (cutter blade) the sterility (high freedom from germs) is ensured in that the sterile medium sweeps at least over the fill opening and thus forces germs of any nature away from the fill opening or does not even allow such access in the direction of the fill opening.

Consideration is given, as sterile media to be moved by the medium delivery device to the fill opening, to sterile air and/or nitrogen and/or other media such as inert gases, hydrogen peroxide, etc. The medium delivery device may move the respective sterile medium in the direction of the fill opening under a specified excess pressure and/or, with the support of an exhaust device as part of the medium delivery device, may move excess sterile medium, but preferably non-viable particles, to the exterior from the site of the fill opening from the molding device. Sterile media such as steam or hydrogen peroxide are employed to sterilize the sterile barrier and the supply lines of the media delivery device. Sterilization of the barrier preferably is effected in advance of beginning of operation, but may be carried out at discrete time intervals during interruptions of production. Sterile medium preferably in the form of an inert gas may

also be used for charging the container, for example, if the content of the product is oxygen-sensitive.

In another advantageous configuration of the method and the device claimed for the invention the sterile barrier is in the form of a plate-shaped cover element moving back and forth with the separating element for separation of the plastic tubes or moves simultaneously with parts of the production mold.

The method and the device claimed for the invention are described in what follows on the basis of two exemplary embodiments shown in the drawing, in which, in diagrammatic form not drawn to scale,

FIGS. 1a,b,c present perspective views of the essential parts of the first exemplary embodiment of a production device;

FIGS. 2a,b,c present perspective views of the essential parts of the second exemplary embodiment of a modified production device.

FIGS. 1 and 2 show parts of a device for production of plastic containers in the blow molding process, a tube 12 of melted plastic material being extruded by means of an extruding means 10 between the two mold halves 14 of a mold 16, which is shown in the opened position in FIG. 1a and in the closed position in FIGS. 1b and 1c. After extrusion of the tube 12 into the opened mold 16, the tube 12 is separated by cutter 28 between the mouth of the nozzle of the extruding device 10 and the upper side of the mold 16. FIGS. 1b, 1c show the mold 16 in the closed position, the parts making up the majority of the parts of the container to be formed from the tube 12, that is, the mold halves 14, are brought together so that the bottom-side welding

edges on the lower end of the tube 12 effect a welding process in order to seal the tube 12 along a welding seam (not shown).

FIG. 1c shows the mold 16 is in a filling position into which the mold has been displaced sideways from the position shown in FIGS. 1a,b oriented toward the extruder means 10. In this filling position the container (not shown) which was previously formed by blowing of blast air through the open filler opening 18 is filled with the respective filling material by way of the fill opening 18. FIG. 1c illustrates the end of the charging mandrel 20 to be introduced into the respective fill opening 18 for this purpose. The vertical reciprocating movement of the charging mandrels 20 is indicated in FIG. 1c by a double arrow 22, as is also the lateral back-and-forth movement of the mold 16 by a double arrow 24 and the potential opening and closing movement of the two jaws 14 of the mold 16 by a double arrow 26. Molding and charging of the container may also be effected by a combined blowing-charging mandrel in place of the charging mandrels 20 and a previously introduced blowing mandrel (not shown). The mold 16 shown is not restricted to production of one or two containers. On the contrary, a plurality of containers positioned side by side in a row is customarily produced. The process of producing only a single container is explained for the sake of greater simplicity of presentation.

In the filling position shown in FIG. 1c the mold is positioned below an area called the sterile filling space not shown in the figures, a space which effects aseptic shielding of the fill opening 18 which has been formed by the preceding process of separation of the tube 12. After the container has been charged, the filling mandrel is moved away upward and the still open movable upper welding or head jaws (not shown) of the mold 16 are brought together so as to effect shaping of container neck and/or simultaneously to seal this neck by welding. The respective production steps are the customary ones up to this point and elements of the bottelpack® system referred to in the foregoing.

FIG. 1a shows the status of operation before separation of the respective extruded tube 12, a heatable blade serving as separating element 28 being mounted at a specified distance or also at zero distance on the front side of a plate-shaped cover element 30 serving as a sterile barrier, and the separating element 28 and cover element 30 are moved back and forth in the directions indicated by the double arrow 32, from a base position as shown in FIG. 1a to an operating position as shown in FIG. 1b and vice versa.

By means of the sterile barrier in the form of a plate-shaped cover element 30 a sterile medium 34 may be transported in the direction of the fill opening 18 by means of media delivery device identified as a whole as 36. Sterile air and/or nitrogen and/or other media such as other inert gases, hydrogen peroxide, etc. qualify as sterile media 34 which are moved to the respective fill opening 18 by the media delivery device 36. For the purpose of transporting the respective sterile medium 34 the plate-shaped cover element 30 has, in the direction of the fill opening 18, medium discharge points 38 as part of the media delivery device, points which are configured as a type of perforations of the plate 30 and permit delivery of the respective medium by way of entry points 40 in the direction of the fill opening, the respective sterile medium 34 being blown in the direction of the fill opening 18. The respective entry points 40, which are also a component of the media delivery device, are present in the rear area of the cover element 30, on the side opposite the narrow front side of the cover element 30 with the separating element or blade 28. Conveyance of the sterile medium 34, especially in the form of sterile air, to the cover plate 30 and through the media exit points 38 in the direction of the fill opening 18 is effected by means of excess pressure.

In order to sterilize the barrier in advance of production proper with the device, provision has been made for conduction of steam or other suitable means such as hydrogen peroxide through the barrier with its openings, in addition to the delivery lines. The sterile medium may then be conducted by way of the sterile barrier to the fill openings for commencement of production proper. If an inert gas such as nitrogen is employed as sterile medium for use of the

sterile barrier, this gas may also be used to keep the container filled with the inert gas. This is a logical step if the specific product with which the container is to be filled is oxygen-sensitive.

Protection is provided for the fill opening 18 itself when, as shown in FIG. 1b, the tube 12 has been separated by the separating element 28, and so when the cover element 30 has been moved to the front position and so covers the point of separation of the two mold halves 14 at least in the area of the fill opening. Consequently, when the media delivery device 36 has been actuated the sterile medium is blown by excess pressure in the direction of the longitudinal axis of the container toward and into the filler opening. If appropriate removal points are provided in the cover element 30, the possibility also exists of washing the interior of the container and accordingly the filler opening 18 by blowing the sterile medium 34 in and immediately exhausting it over other parts of the media delivery device 36. However, delivery of sterile medium may be made completely independent of the exhaust output of the respective parts of the media delivery device 36.

The media delivery device 36 may have an exhaust device designated as a whole 42, preferably one in the form of a vacuum device which by means of a specified negative pressure carries the respective sterile medium 34 away from the filler opening 18 by way of central evacuation points 44. The respective evacuation device as part of the media delivery device 36 is used chiefly for the purpose of evacuating the non-viable particles generated during separation of the tube. In the process, overflowing sterile medium may be evacuated with them and be removed from the device. By preference equilibrium exists between the amount of medium flowing out of the perforation as a result of excess pressure and the amount of medium which is evacuated from the evacuation device 42.

The possibility of removal by way of the central evacuation points 44 is correspondingly indicated in the figures by arrows and, in addition, the exhaust or vacuum device 42 surrounds

the plate-shaped cover element 30 as a frame in the form of frame components 46 positioned in relation to each other so as to form a rectangle, but ones which also allow entry into and departure from the sterile barrier in the form of the cover element 30.

In order to achieve an especially good germicidal effect, the sterile medium is conducted at a temperature meeting the sterility requirements, for example, so that the medium 34 is at a temperature above 120°C, preferably at a temperature in the range of 150°C to 200°C. In addition or as an alternative, the sterile barrier and thus the cover element 30, which preferably is made of stainless steel materials, may be heated to the temperature range in question. If the evacuation device 42 has sufficient output potential, the medium 34 need not be delivered by way of a pumping or blowing device. In some instances the exhaust output is sufficient to ensure conduction of the medium and accordingly flow through the respective filler opening 18.

If, as is illustrated in FIG. 1b, the tube section is separated by the separating element 28 to form the filler opening, the closed mold 16 comes to the charging station as shown in FIG. 1c, sterile safety being ensured by the sterile filling space (ASR), as has already been pointed out. After the mold has been returned to the initial position as shown in FIG. 1a, a tube section may then be extruded into the shaping components of the mold halves 14 to form the container.

The embodiment shown in FIGS. 2a,b,c to a great extent resembles the first embodiment shown in FIGS. 1a,b,c and will be explained only to the extent that it differs substantially from the preceding exemplary embodiment shown in FIG. 1. In the modified solution the sterile barrier in the form of the cover element 30 is spatially separated from the separating element 28 and may be moved independently of the latter. By preference the cover element 30 is associated with at least one of the mold halves and, as is illustrated in FIG. 2b, the two mold halves 14 are moved to be positioned under the sterile barrier. The movement of the cover element 30 may be synchronized with that of the mold halves 14. In an association of elements such as this, when the mold 16 is moved to the charging station as shown in FIG. 2c, the sterile barrier in the form of the cover element 30 logically is moved along with it. However, as in the case of the embodiment shown in FIGS. 2a,b,c, the possibility also exists of carrying out the following process sequence, specifically, one in which the mold is moved to the separating element 28 (cutter), which cuts and simultaneously moves the plate up as sterile barrier (precisely as in the illustration in FIG. 1). The mold with the plate-shaped cover element 30 then moves into the filling position. After it has arrived the plate moves backward so that the blowing and charging mandrel may move into the opening 18. After the container has been closed along its head side, the open mold together with the plate as sterile barrier moves back to the respective initial tube position.

In the embodiment shown in FIG. 2, the separating element 28 is in addition positioned vertically at the same height, but by preference below the cover element 30.

The method claimed for the invention is by preference applied for simultaneous production of several containers, preferably ones in the form of low-volume containers such as ampoules. The containers may be formed by blow molding or, especially in the case of very low-volume containers, also by vacuum molding.